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Impact Analysis of a Fast Track Protocol Implementation After Bariatric Laparoscopic Roux-En-Y Gastric Bypass in A General Surgery Unit

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Abstract

Setting: fast track protocols after bariatric surgery had been firstly introduced in large-volume specialized bariatric centers, demonstrating to improve patient's recovery and hospitalisation; however, feasibility and safety should be still investigated in general surgery units with medium-volume bariatric operations.

Objectives: the aim of this study was to assess feasibility, safety and cost-efficacy of implementation of Enhanced Recovery After Bariatric Surgery (ERABS) criteria to bariatric surgery in a medium-volume center.

Methods: from October 2014 to January 2017 clinical records of all consecutive patients operated for Laparoscopic Roux-en-Y Gastric Bypass (LRYGB) by experienced surgeons (i.e who performed at least 50 procedures) were retrospectively collected and analysed. Data included demographic and clinical features, operative remarks, hospitalisation, postoperative complications and re-admissions after discharge. Patients were divided in two groups: group A (treated with conventional protocol) and group B (treated by ERABS protocol). Student's T-test and CHI-square test were used when appropriate. A p-value <0.05 was considered significant.

Results: the overall sample of the study consisted of 88 patients were included in the study: the two pre- and post-ERABS groups were homogeneous in terms of gender, age, Body Mass Index (BMI) at the beginning of the path, at discharge and one month after surgery, copathologies associated with obesity, previous abdominal and bariatric surgery. Regarding the surgical procedure, statistically significant shorter operative times were found in the ERABS group with an average of 67.25 vs 97.2 minutes ($p<0.001$). Moreover, ERABS group had significant shorter stay in Intensive Care Unit (ICU) (0.02 days' vs 0.32, $p=0.014$) and semi-intensive care unit (SICU) (0.23 vs 2.02 days $p<0.001$). No differences were found in terms of postoperative complications, neither in re-intervention or re-admission rate after discharge.

Conclusions: The implementation of ERABS protocol in a General and Emergency Surgery Unit with bariatric activity demonstrated to be safe and feasible, leading to reduction of operative times and ICU admission without increasing complications, reintervention or re-hospitalization rates.

Keywords: Complications; ERABS; Gastric bypass; Hospitalization

Abbreviation: ERABS: Enhanced Recovery After Bariatric Surgery; LRYGB: Laparoscopic Roux-en-Y Gastric Bypass; BMI: Body Mass Index; ICU/SICU: Intensive Care Unit/Semi-Intensive Care Unit; LMWH: Low-Molecular-Weigth Heparin; PONV: Postoperative Nausea and Vomiting; PPI: Protonic Pump Inhibitors; COPD: Chronic Obstructive Pulmonary Desease; OSAS: Obstructive Sleep Apnea Syndrome; CPAP: Continuous Positive Airway Pressure; LOS: Length of Stay

Background

The ERAS protocols (acronym of Enhanced Recovery After Surgery) have changed the approach of peri-operative care regarding many procedures performed today. Kehlet was one of the first to describe a set of measures to promote early ambulation and discharge with a rapid return to normal lifestyle after surgery [1]. The ERAS program is a set of evidence-based protocols that include pre-, intra- and post-operative measures that aim to standardize and optimize perioperative care in order to reduce stress response by promoting and enhancing patient recovery. In summary, the program includes: extensive pre-operative counseling, short-acting anesthetics, pain and post-operative nausea control, moderating the use of opioids, elimination of unnecessary invasive monitoring, early ambulation and feeding [2]. Each of these interventions has proven to be independently favorable and beneficial to the patient, while their contemporary use seems to have a synergistic effect [1]. Evidence of the substantial benefits of ERAS actually exists for colorectal, thoracic and urological surgery [3,4].

Some Authors reported that even in elective laparoscopic gastric resections some principles of the ERAS protocol (absence of naso-gastric tube and abdominal drainage, early resumption of oral feeding and optimization of analgesia) may be successfully applied, without increasing significantly postoperative morbidity [5]. Therefore, several authors have proposed and applied these protocols to bariatric surgery. However, many surgeons are still reluctant to apply a fast track protocol because the obese patients have peculiar characteristics (reduced cardiovascular, respiratory and metabolic reserves) which make them frails. Furthermore, any surgical complications may be insidious but potentially life-threatening or even rapidly fatal. Specialized, high-volume referral bariatric centers started some years ago to successfully apply fast track protocols after bariatric operations (mainly gastric bypass or sleeve gastrectomy). On the other hand, such proocols are still poorly adopted by several units of General and Emergency Surgery with a remarkable volume of bariatric operations (at least 100 per year).

The aim of the study was to compare the clinical outcomes (days of hospitalization, re-surgery, re-admissions in hospital within 30 days and complications) of two groups of patients undergoing laparoscopic gastric bypass before and after the application of a tailored protocol based on ERABS (Enhanced Recovery After Bariatric Surgery) principles.

Materials and methods

The ERABS program is a set of protocols applied to bariatric surgery and can be divided into three phases:

- Preoperative phase: taking care of the patient and optimizing his state of health to allow him to get to the surgery in the best conditions.
- Operative phase: optimization of surgical and anesthetic maneuvers aimed at minimizing the response to surgical stress.
- Postoperative phase: multimodal approach to patient rehabilitation, optimization of analgesia, reduction of postoperative nausea and vomiting, early ambulation and feeding, removal of unnecessary devices.

Despite the formulation of a protocol, flexibility and individualisation must however be made possible according to local setting [6].

The following measures were adopted in our centre:

- **Pre-Operative Phase:** Evaluation and optimization of organic functions Ensure a good nutritional status by a diet developed by the nutritionist; improve physical activity with a daily exercise plan Minimum fasting No mechanical intestinal preparationAntitromboembolic prophylaxis with LWMH (Low-molecular-Weigth Heparin), continued for about three weeks after the operation. A light diet allowed the evening before surgery
- **Operative Phase:** Antibiotic prophylaxis (Cephalosporine 2 gr) Premedication if necessary (no routine use of benzodiazepines). Targeted administration of fluids Minimize tissue manipulation and Minimize operating times during surgery. Not positioning of nasogastric tube Pneumatic compression leggings until the beginning of autonomous mobilization. Not routine invasive blood pressure monitoring Not routine positioning of the central venous catheter Curarizing drugs (Rocuronium) used only if necessary (e.g. insufficient abdominal space for laparoscopy). Prevention of Postoperative Nausea and Vomiting (PONV) trough prokinetics, anti-hemetics, steroids.

- **Post-Operative Phase:** Multimodal anesthesia, adequate and pre-emptive analgesia (Paracetamol 1gr, Ketorolac 30mg, trocar accesses infiltration with a long-term local anesthetic such as 10ml of 0.75% Ropivacain). Extubation in the operating room and observation and monitoring in Recovery Room for two hours (paying particular attention to body temperature, pain, heart rate and respiratory rate, blood pressure, arterial blood gases and PONV). Admission to ICU only in very selected cases: BMI> 45 kg/m^2 with relevant co-morbidities, difficulty in controlling the airways, possible intraoperative surgical or anesthesiological complications. Blood tests performed only on medical judgment based on the quality of the output of the drainage and on any indications defined intraoperatively for increased risk of bleeding.

Early removal of drainages or other devices if present. Early enteral nutrition Early forced ambulation. Standardized surgical technique of LRYGB performed at our center is standard. The stomach is completely divided so as to obtain in the upper portion of the stomach a pocket of about 30ml which is anastomosed with the small intestine. A second anastomosis is performed between the alimentary loop and the biliopancreatic one [7]. Therefore, three ways are created: the alimentary section, the section bilio-pancreatic and the common tract.

In the ERABS program few modifications are made: separation of the omentum (Peterson space) is no longer performed to place the jejunal loop in the sovramesocolic region and the blue test to assess effectiveness of the gastro-jejunal anastomosis is performed with the calibrating tube which is removed immediately after the surgery, without positioning nasogastric tube.

In the ERABS the resumption of oral intake was anticipated by about one day (in comparison to the pre-ERABS) according to the following scheme developed on the basis of the combined study of surgeons and nutritionists.

Two glasses of water are allowed on 1st post-operative day, on the 2nd day: yoghurt and a soup for lunch and a yoghurt for dinner. From the 3rd to the 6th day a semi-liquid diet of 600 Kcal with 32g of protein and from the second to the fifth post-operative week a semi-solid personalized diet of about 900-1000 Kcal and 40-50g of protein are developed by the nutritionist. The discharge criteria consist in assessing good general condition, optimal pain control, tolerated semi-solid diet, functioning intestine and good autonomous mobilization. Low Molecular Weight Heparin (LMWH) for 3 weeks, Protonic Pump Inhibitors (PPI) for two months and multivitamin complexes are prescribed to the patients.

Study design

All consecutive patients who underwent LRYGB from October 2014 to January 2017 in Azienda USL-IRCCS di Reggio Emilia were retrospectively reviewed. Patients were classified in two groups with same number of patients: group A (patients non treated by ERABS protocol) and group B (patients treated by ERABS protocol). Such protocol was applied to all patients operated from the time of its introduction (February 2016) in our clinical practice, meaning that there were no criteria to deny fast track protocol to any particular subset of patients. All patients were included in the study excepts for 5 patients operated by less experienced surgeons (who had performed less than 50 procedures) [8] to avoid bias of surgical data (lenght of operation and postoperative complications) due to learning curve completion.

Patients selection criteria

Patients scheduled to bariatric surgery were examined by a multidisciplinary team dedicated to bariatric surgery (surgeon, anesthesiologist, diabetologist, psychologist and nutritionist). Surgery was indicated in patients aged 18-65 and having a BMI>40kg/m^2 with no comorbidities or a BMI >35 kg/m^2 and one or more of obesity-related comorbidities (type 2 diabetes mellitus, hypertension, coronary artery disease, Obstructive Sleeping Apnea Syndrome (OSAS), arthropaties. Conversely, absolute contraindications were untreated endocrinopaties (secondary obesity) and psichiatric disorders (psychosis, schizophrenia, binge eating disorder or night eating disorder).

During preoperative pathway patients underwent an extensive work-up assessment and were made aware of the risks and the modalities of the surgical intervention with further discussion with the surgeon and through informed consent elaborated by the S.I.C.O.B. (Italian Society of Surgery of Obesity and metabolic diseases) [9]. (http://www.sicob.org/area_04_medici/50_consenso_informato.aspx).

Data collection

The collected data included demographic details (age, sex), presence of co-pathologies frequently associated with obesity such as diabetes, smoking, hypertension, COPD (Chronic Obstructive Pulmonary Desease), OSAS (Obstructive Sleep Apnea Syndrome) with use of home C-PAP (Continuous Positive Airway Pressure), arthropathies, lower limb varices, tireopathies, previous abdominal surgery and previous bariatric procedures; BMI at the beginning of the preoperative path, BMI at discharge and BMI one month after surgery. Regarding the data related to the surgical intervention the overall operative time and laparotomic conversion were considered (secondary outcomes). Data about hospitalisation included: lengh of stay in Intensive Care Unit (ICU), in SICU (Semi-Intensive Care Unit), in the ward and overall hospitalisation; day of removal of nasogastric tube, abdominal drainage, mobilization and resumption of oral intake (secondary outcomes). Regarding the outcome, re-operation and readmission within 30 days and complications (ranked by severity according to the Dindo-Clavien classification) [10] were taken into consideration and represented primary outcomes.

Statistical analysis

Statistical analysis was performed using SPSS software v.23 (SPSS Inc., Chicago, Illinois). Averages of continuous variables between the two groups were compared by Student's t test for independent samples, while for the categorical variables the Chi –Square test was used to assess differences in the distribution between the two groups. As a threshold for significance, a value of $p < 0.05$ (2-tail test) was chosen.

Results

A total number of 88 patients were included in the study, 44 in pre-ERABS group and 44 in ERABS group. Demographic and clinical details are shown in Table 1. There were no baseline differences between the two groups (Table 1). Patients were predominantly women in both groups. Median preoperative BMI of the participants was 46 and 45, while at 1 month from surgery it dropped to 42 in both groups. Regarding surgical procedure, the operating time was significantly shorter in the ERABS group (67.25 Vs 97.02 minutes) (Table 2): all the operations were performed by experienced surgeons, therefore the difference was due to change of surgical tecnique, as described above, and not to learning curve completion. On the other hand, the rate of laparotomic conversion was minimal in both groups, despite previos bariatric/abdominal surgery that was found slightly more frequently in ERABS group.

	Pre-ERABS	ERABS	p
Age	44.36 (+/-11.36)	41.39 (+/- 9.79)	0.191
Sex (M/F)	11/33	10/34	0.803
Initial BMI	48 (+/- 7.40)	46.86 (+/-6.38)	0.491
BMI at discharge	46.09 (+/-8.23)	45.20 (+/-5.87)	0.561
BMI one month after surgery	42.34 (+/-6.75)	42.35 (+/- 6.01)	0.999
Smoking (yes/no)	10/34	10/34	1
Diabetes (yes /no)	10/34	9/35	0.796
Hypertension (yes /no)	18/26	23/21	0.285
COPD (yes/no)	6/38	2/42	0.138
OSAS (yes/no)	12/32	7/37	0.195
Home CPAP(yes/no)	1/43	3/41	0.306
Arthropathy (yes/no)	10/34	12/32	0.622
GERD (yes/no)	14/30	10/34	0.338
Leg varicose vains (yes/no)	4/40	3/41	0.694
Tireopathy (yes/no)	9/35	8/36	0.787
Previous abdominal surgery (yes/no)	21/23	28/16	0.133
Previous bariatric surgery (yes/no)	9/35	14/30	0.285

Table 1: Demographic and clinical characteristics of the population.

	Pre ERABS	Post-ERABS	p
Operating time (minutes)	97.02 (+/-26.92)	67.25 (+/-15.09)	<0.001
Laparotomic conversion (yes / no)	1/43	0/44	0.315

Table 2: Results of the surgical procedure.

Regarding postoperative outcome, the total amount of hospital stays in ICU (0.02 vs. 0.32 days, p=0.014) and SICU (0.23 vs. 2.02, p<0.001) was significantly lower in ERABS group due to different, less restrictive criteria used for admission after surgical operations. Also the total in-hospital stay was reduced although not significantly (6.91 vs 8.14 days). Obviously we have a slight greater duration of hospital stay in ward in the ERABS group (6.66 vs. 5.80 days) because the patients in general discharged from the Recovery Room are transferred to the ward. Moreover, ERABS patients showed better "functioning" parameters, especially in terms of nasogastric tube duration (0 vs 1.14 days, p<0.001) and mobilization (1 Vs 1.6 days, p=0.004). Data are showed in Tables 3,4. Other parameters as drainage removal and resumption of oral intake were performed earlier in ERABS group, although mean time did not reach statistical threshold for significance. Adoption of ERABS protocols regarding either operative technique and postoperative care did not impact on major complications, defined by re-admission or re-intervention within 30 days: only one surgical reoperation was necessary in both groups and only in the pre-ERABS group there was a re-admission to the hospital.

	Pre- ERABS	Post-ERABS	p
Hospital stay in ICU (days)	0.32 (+/-0.771)	0.02 (+/-0.151)	0.014
Hospital stay in SICU (days)	2.02 (+/-1.23)	0.23 (+/-1.24)	<0.001
Hospital stay in ward (days)	5.80 (+/-3.758)	6.66 (+/-4.38)	0.324
Total hospital stay (days)	8.14 (+/-3.83)	6.91 (+/-4.63)	0.179
Nasogastric tube (days)	1.14 (+/-1.11)	0	<0.001
Drainage (days)	5.27 (+/-3.72)	4.8 (+/-4.66)	0.597
Day mobilization	1.59 (+/-1.11)	1.07 (+/-0.39)	0.004
Restart food oral intake	3.36 (+/- 1.102)	2.95 (+/- 2.011)	0.24

Table 3: Postoperative outcome.

		pre-ERABS	ERABS
Reoperation within 30 days	yes	1	1
	no	43	43
Readmission within 30 days	yes	1	0
	no	43	44

Table 4: Re-intervention and readmission within 30 days.

We have seen a total of six complications in both groups that we have classified according to the Clavien-Dindo scheme (Tables 5,6) [10]. In the pre-ERABS group we had 3 Grade 1 complications that consisted of bleeding that required no transfusion, a wound infection and a thrombophlebitis in the same patient; two complications of grade 2: anastomotic leak (both in patients already undergoing previous bariatric surgery) treated conservatively with antibiotic therapy and leaving the drainage in place leading to an increase in days of hospitalization; a grade 3B complication ie Peterson's internal hernia that required surgery under general anesthesia. In the ERABS group we had three grade 1 complications consisting of bleeding without the need for transfusion; two grade 3A complications: an anastomotic leak in a patient who had previously undergone bariatric surgery and was treated with CT-guided percutaneous drainage of the collection; a pleural effusion resolved with placement of chest drainage. Finally, we observed a Grade 3B complication: a perforation of gastric remnant that required surgical reintervention and one-day hospitalization in intensive care and eight days in SICU. Distribution of frequencies resulted not significant (p=0.28). Finally, we can note that out of 44 patients operated pre-ERABS the intervention was postponed in 4 patients due to unavailability of beds in ICU while this has never happened in the ERABS group (p=0.041) due to less restrictive criteria for admission in surgical ward after the operation.

	Pre-ERABS	ERABS	p
Grade 1	3	3	0,28
Grade 2	2	0	
Grade 3A	0	2	
Grade 3B	1	1	
Grade 4	0	0	
Grade 5	0	0	

Table 5: Postoperative complications according to the Dindo-Clavien classification.

	Pre-ERABS	ERABS	p
yes	4	0	0.041
no	40	44	

Table 6: Intervention postponed due to unavailability of place in ICU.

Discussion

One of the first experiences of fast track after bariatric surgery was in 2005, when McCarthy and co-workers reported a discharge within 84 hours of surgery in 84% of cases on 2000 consecutive patients operated by LRYGB [11]. Of these, 1.7% (n = 34) was readmitted to hospital within 30 days, the rate of early complications was 1.9% (n = 38), and late ones of 4.3% (n = 86). Mortality reported was 0.1% (n=2). They demonstrated, both with univariate and multivariate analysis that the surgeon's experience,

patient age, BMI, co-morbidities and an intraoperative steroid bolus are the predictors of early discharge. Authors highlighted the importance of the standardization of peri-operative care but specific fast track protocols were being mentioned. Their conclusions were consistent with comparable results reported by Bergland et al. in 2008 underlining the importance of standardized anesthetic methods [12]. The same group described a more detailed fast track protocol in a large patient cohort later in 2012 [13].

In recent years, a growing number of articles have dealt with outcomes following bariatric surgery with ERABS criteria, demonstrating the interest in achieving a standardisation of intraoperative and postoperative care of obese patients [14,15], with similar low complication rates. However, almost all publications come from high volume tertiary specialized bariatric centers. Elliott and coll. in a recent systematic review stated that although there is evidence of the feasibility of ERABS treatment in patients undergoing LRYGB, there is still insufficient data to promote its routine adoption outside high-volume bariatric centers [16]. Therefore, it should be interesting to know if ERABS programs could be safely applied in hospitals with a lower volume of patients and less specialized (e.g. General and Emergency Surgery Unit with non-sporadic bariatric activity). A study on 388 patients of 2016 Tilda et al. shows that the results, usually reported by specialized centers with high volume, are potentially reproducible in less specialized centers with lower volume [2]. In fact, the mean of the LOS (Length of Stay) was 1.3 days with a reoperation rate of 3.4% and readmission rate of 3.9% within 30 days. There was an 8.5% morbidity as divided according to the classification of Clavien Dindo: grade I-II 5.6%, grade IIIa-b 2.6%, grade IVa-b 0.6%, grade V 0. They concluded that each patient can be treated according to the ERAS protocol outside centers specialized in bariatric surgery with high patient volume.

Award and coll. in a study on 226 procedures (of which 150 were gastric bypasses) reported a 37% discharge on the first postoperative day and readmission within 30 days in 2.7% with 4% complications [17]. Raftopoulos and coll. in a study of 820 patients subjected to gastric bypass by the same surgeon state that the discharge in the first postoperative day after gastric bypass can be achieved without increasing the risk of major complications, mortality, reintervention, re-admission in the ward, access to the emergency room but above all without reducing patient satisfaction [18]. Mannaerts et al. in a study of 1967 patients undergoing bariatric surgery, of which 1313 procedures following ERABS implementation noted a significant reduction in operative time and a significant decrease in LOS from 3.2 to 2 nights ($p < 0.001$) [19]. There were significantly more complications (20.7 Vs 16.1%, $p = 0.013$) in ERABS patients although there were no significant differences when considering only major complications. The confirmation was also given by a Systematic Review with Metanalysis and Trial Sequential Analysis published in 2017 by Singh et al. who state that the implementation of ERAS protocols in bariatric procedures is effective in reducing postoperative hospital stay without compromising patient safety and long-term results; indeed, the rates of minor complications increase without any significant effect on morbidity [20].

Our study compared to the previous ones has a smaller cohort since the ERABS protocol was adopted only in February 2017; to the best of our knowledge, there are currently few data in literature concerning the application of the ERABS protocol in a general surgery with a medium-volume of bariatric operations. With the implementation of ERABS protocols we were able to reducing operative times, admission in higher care intensity wards, time of immobilisation and use of devices as naso-gastric tube. In particular, we managed to reduce the total in-hospital stay from 8.14 days to 6.91 days, but above all by nearly eliminating the admission in ICU (0.02 days' vs 0.32) and in SICU (average of 0.23 days' vs 2.02) with a remarkable reduction of costs and shortening of waiting list, because bedside availability in higher care intensity wards was no more mandatory. So in a setting with limited resources this may avoid unnecessary costs and optimize operative theatre usage. These data (reduction of operative times, postoperative hospital stay) are consistent with those reported in literature, despite our post-operative average hospital stay is still remarkably longer compared to the US and Northern European specialized bariatric centers who started an ERABS program several years ago. In this scenario a valid post-discharge assistance (consisting in phone-call counseling and dedicated outpatient service) would be crucial to further reduce in-hospital stay without compromising patient's safety and satisfaction.

The results in terms of complications/hospital re-admission and re-operation demonstrated that application of ERABS protocols could be feasible and safe for patients even in a General Surgery with bariatric activity: neither the total amount of complications (differently from Mannaerts and coll.) [19] nor their distribution in Dindo-Clavien cathegories significantly differed between pre-ERABS and ERABS groups. Finally, it has to be pointed out that efficacy of LRYGB was not affected by ERABS criteria and faster resumption of oral feeding, as demonstrated by the same drop of BMI 1 month after surgery in both groups.

Conclusions

In summary, this study demonstrates that implementation of the ERABS protocol in a general surgery with medium-volume bariatric activity is feasible and safe for patient, with a consensual reduction of costs of hospitalization and a better optimisation of intervention scheduling. The standardization of anesthetic protocols, surgical technique, the presence of a dedicated medical and nursing team, preoperative counseling and follow-up by a multidisciplinary group are crucial to maintain good clinical outcomes, patient's satisfaction, procedure efficacy and to strive toward excellent

results of specialized, high volume bariatric centers.

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